IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 3 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' REPLY TO OPPOSITION TO MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF DANIEL ELLIOTT, M.D.

Defendants Ethicon, Inc. Ethicon LLC, and Johnson & Johnson (collectively "Defendants") submit this reply in further support of their motion to exclude certain general opinions of Daniel Elliott, M.D.

I. The Court should preclude Dr. Elliott from testifying that non-synthetic mesh procedures are a safer alternative for the surgical treatment of SUI, because his opinions are unreliable.

Dr. Elliott is not competent to testify that TVT Devices are more dangerous than non-synthetic mesh sling procedures, because Dr. Elliott has conceded that he does not even know TVT Device complication rates and he has not cited any reliable studies that support his opinion. Ex. G to Doc. 2082, 9/26/15 Dep. 110:13-17, 196:7-14. Plaintiffs do not and cannot deny that the crux of Dr. Elliott's opinions is a perceived lack of data. Based on this perceived lack of data, Dr. Elliott wrongly assumes a worst-case scenario and relies solely on his personal experiences. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 521 (S.D. W. Va. 2014) (finding that an expert may not assume a worst-case scenario).

Dr. Elliott's personal experiences, however, do not afford a reliable basis to provide broad opinions. Just because Dr. Elliott—who may be exceptionally skilled with traditional surgical procedures—has had good results with those procedures does not mean that his success may be broadly translated to others.

The fatal fallacy of Plaintiffs' logic is illustrated in the following hypothetical: Suppose Nike and Titleist are engaged in a lawsuit, and an issue involves which company's golf ball travels farther. The proof shows that the industry driving average (averaging both pro and semi-pro golfers) for Titleist golf balls is 250 yards, which is greater than the Nike average. Nike seeks to present as an expert witness Tiger Woods, who testifies as follows: "I have never hit Titleist golf balls. I don't know how far most golfers drive Nike golf balls, but I know that I drive Nike golf balls an average of 300 yards. Because I personally drive Nike golf balls farther than the Titleist industry average, it is my expert opinion that Nike golf balls travel farther than Titleist golf balls." This would be junk science

II. The Court should preclude Dr. Elliott from offering design opinions, such as testifying that other synthetic mesh devices offer safer alternatives.

A. Dr. Elliott does not believe that there are safe synthetic mesh alternatives to TVT Devices.

In their opposition, Plaintiffs distort Dr. Elliott's opinions and suggest that he really did not mean that no synthetic mesh products should be used; instead, he meant to say that "all synthetic mesh products and tensioning pose some risks – but, different levels of risk." Doc. 2952, p. 10. In fact, Dr. Elliott unequivocally testified that *all* mesh products are "unsafe" and that "[m]esh should not be placed in the vagina." Ex. G to Doc. 2082, Elliott 9/26/15 Dep. 143:11-14, 144:16-18, 285:22. Given that Dr. Elliott does not believe that any pelvic mesh

products should be placed inside of a woman, it is impossible for him to testify that a superior product design existed.

B. Lighter Weight/Larger Pore Size Mesh

Dr. Elliott cannot credibly argue that a device with a lighter weight/larger pore mesh would have been more suitable given that, as noted above, he does not believe that any mesh devices are suitable. Notwithstanding Plaintiffs' suggestions, Dr. Elliott could not identify any studies showing that lighter weight mesh is safer than the mesh in TVT and effective for the treatment of SUI. *Id.* at 238:5-241:15. Dr. Elliott could only attempt to extrapolate data from hernia mesh and pelvic organ prolapse devices and apply it to SUI devices, such as TVT. Yet, those devices are different devices with no sheath, different trocar approaches, different placement, and different volume of polypropylene.

As noted by Dr. Marc Toglia, the bulk of studies related to non-SUI mesh devices is "Level 5 data, that you really can't draw any clinical inference or--- or application directly to the TVT device." Ex. A hereto, Toglia 10/2/15 Dep. 324:5-10. Where the Level 5 evidence is incongruent with Level 1 evidence, the lower level evidence is significantly less useful. *Id.* at 327:11-22. Dr. Toglia has explained that research involving hernia mesh is lower-level evidence. *Id.* at 325:14-326:6; Ex. B hereto, Toglia TVT Rep. at 23, 25. For comparison purposes, it would be difficult to compare a 1.1 cm strip of TVT mesh to large mesh sheets, because the volume difference is so large. *Id.* at 25-26.

In fact, Plaintiffs' position that non-SUI mesh data may be extrapolated is inconsistent with Dr. Elliott's own lament that data concerning lighter weight/larger pore SUI mesh "does not exist and it should exist." Ex. G to Doc. 2082, Elliott 9/26/15 Dep. 273:2-275:9. Thus, he concedes that his opinion is hampered by the lack of data. Plaintiffs cite no study showing that

lighter weight, larger pore mesh would be as efficacious at treating SUI. Thus, Dr. Elliott's opinions do not pass the standard for reliability.

III. The Court should preclude Dr. Elliott from criticizing the cut of TVT mesh.

As it relates to Dr. Elliott's criticisms of both laser-cut mesh and mechanically-cut mesh, Plaintiffs assert that "Dr. Elliott does not seek to testify that one is necessarily safer than the other." Doc. 2952, p. 12. If so, then there is no reason for Dr. Elliott to testify about this issue at all, and his opinions are irrelevant.

According to Plaintiffs, "[i]nstead, Dr. Elliott will explain to the jury the unique problems associated with mechanically-cut mesh versus laser-cut mesh." *Id.* In other words, in a mechanically-cut mesh case, Plaintiffs want to elicit testimony from Dr. Elliott that would suggest to the jury that laser-cut mesh has fewer problems; and in a laser-cut mesh case, Plaintiffs want to elicit testimony from Dr. Elliott that would suggest to the jury that mechanically-cut mesh has fewer problems. Such testimony would tend to confuse the issues, mislead the jury, and prejudice a party, and therefore, should be excluded under Rule 403. As it did with the Wave 1 cases, the Court should preclude Dr. Elliott from offering these opinions. *See In re: Ethicon, Inc. Pelvic Repair Sys. Litig.*, 2016 WL 4500766, at *5 (S.D. W. Va. Aug. 26, 2016).

Finally, Plaintiffs do not dispute that Dr. Elliott has cited no medical literature that support his opinions about "spiky" edges, roping, curling, fraying, and particle loss.

IV. The Court should not allow Dr. Elliott to speculate about the duties of a medical device manufacturer.

A. Research/Testing

Recognizing that this Court has precluded urologists and pelvic surgeons from critiquing testing performed by Ethicon, *see, e.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 723 (S.D.

W. Va. 2014)[1], Plaintiffs attempt to distinguish this Court's rulings by claiming that "Dr. Elliott has no intention to opine on the *legal adequacy* of the testing conducted by Ethicon, but rather on the *factual* underpinnings of whether or not testing was conducted." Doc. 2952, p. 13. But Dr. Elliott's reports criticize the types of testing relied upon by Ethicon. *See, e.g.,* Ex. C to Doc. 2082, TVT Report at 37.

In any event, there is nothing about Dr. Elliott's background as a urologist that would substantially assist the trier of fact in determining the simple factual question of whether or not testing was conducted; either it was or it was not. As this Court has appropriately noted, "[w]hether Ethicon studied certain issues, provided information, or provided guidance are all examples of corporate conduct," that are beyond the purview of expert testimony. Ex. K to Doc. 2082, *Bellew v. Ethicon, Inc*., No. 2:13-cv-22473, Order at 18 (S.D. W. Va. Nov. 20, 2014).

In truth, Plaintiffs hope to misuse Dr. Elliott as part of an attack on Ethicon for purportedly not conducting testing or studies. Dr. Elliott is not competent to opine when a manufacturer should conduct testing or studies or the appropriate levels of such testing/studies. Further, he could only speculate improperly about what any hypothetical testing/studies would have revealed. Consistent with its prior rulings, the Court should disallow such testimony.

B. Adverse Event Reporting

Plaintiffs assert that Dr. Elliott does not "opine on the collecting or reporting of adverse events." Doc. 2952, p. 15. Yet, on page 55 of his Prolift report, Dr. Elliott states that Ethicon "fail[ed] to properly evaluate and act in response to adverse event reports." Ex. F to Doc. 2082.

[1] In that case, the Court noted that "[t]here is no indication in the record that Dr. Blaivas has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake." *Id.*; *see also In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500767, at *5 (S.D. W. Va. Aug. 26, 2016) (same).

Plaintiffs raise no arguments in opposition to Ethicon's motion to exclude such testimony.[2] Accordingly, and for the reasons set forth in Ethicon's initial brief, the Court should preclude such testimony.

C. Training

Aside from the fact that a medical device manufacturer does not even owe a duty to train,[3] physician training "seem[s] to say very little about the state of the product (i.e., whether or not it was defective) when it went on the market." *In re: Ethicon*, 2016 WL 4582220, at *5. Plaintiffs do not explain what special knowledge Dr. Elliott, as a pelvic surgeon, has that would enable him to critique any alleged duties owed by a manufacturer. In their response, Plaintiffs suggest that Dr. Elliott's criticisms of training will be limited to a critique of the adequacy of the IFUs. Doc. 2952, p. 16. To the extent that Dr. Elliott seeks to criticize training beyond what is set forth in the IFUs, he is not qualified to do so and his opinions are unreliable.

V. The Court should preclude Dr. Elliott from testifying about alleged mesh degradation, shrinkage, contraction, and other biomaterials opinions.

A. Degradation

As with their opposition to Ethicon's Wave 1 challenge of Dr. Elliott's degradation opinions, Plaintiffs merely cite pages 253-254 of Dr. Elliott's September 26, 2015 deposition in support of their suggestion that Dr. Elliott has reliably attributed alleged polypropylene degradation to complications. Doc. 2952, p. 18 (citing Ex. 3 therto at 253:16-254:6).[4] Those pages simply do not show that Dr. Elliott has reached such an opinion within any degree of

[2] In response to Ethicon's motion to exclude these opinions in the Wave 1 cases, Plaintiffs stated that Dr. Elliott will not "offer opinions or testimony about the FDA regulations or the process of collecting and reporting adverse events to the FDA." Doc. 2181, p. 16.

[3] *See, e.g., Woodhouse v. Sanofi-Aventis U.S. L.L.C.*, 2011 WL 3666595, at *3 (W.D. Tex. June 23, 2011); *Adeyinka v. Yankee Fiber Control, Inc.*, 564 F. Supp. 2d 265, 286 (S.D. N.Y. 2008); *Lemon v. Anonymous Physician*, 2005 WL 2218359, at *2 (S.D. Ind. Sept. 12, 2005).

[4] Plaintiffs also assert that Dr. Elliott has cited the Clave study, but they do not show how that study supports a connection between degradation and clinical harm.

medical certainty. In fact, Dr. Elliott lamented that he could not reach such an opinion due to the absence of studies. Ex. G to Doc. 2082, Elliott 9/26/15 Dep. 254:7-18.

In short, Plaintiffs have articulated no reason that the Court should depart from its Wave 1 ruling that Dr. Elliott's opinions about degradation are unreliable and inadmissible. *See In re: Ethicon*, 2016 WL 4500766, at *3.

B. MSDS Sheet

Plaintiffs concede that "Dr. Elliott will not testify as to the MSDS." Doc. 2952, p. 18.

C. Cytotoxicity

Plaintiffs do not appear to offer any response to Ethicon's argument that Dr. Elliott's opinions about cytotoxicity should be excluded because neither he nor anyone else can reliably link cytotoxicity with any clinical harm. Accordingly, the Court should exclude these opinions.

D. "Barbed-wire effect"

Plaintiffs do not oppose Ethicon's challenge to Dr. Elliott's assertion that mesh "creates a '*barbed-wire*' effect." *See* Doc. 2815, p. 17 (citing Ex. F to Doc. 2082, Prolift Report at 34). Therefore, the Court should exclude this opinion.

VI. The Court should not allow other opinions beyond Dr. Elliott's expertise and/or that are otherwise improper.

Plaintiffs do not object to the arguments set forth in Section VI of Ethicon's initial brief, and therefore, the Court should preclude Dr. Elliott from: (a) speculating about Ethicon's alleged knowledge and corporate conduct; (b) testifying about a medical condition that a Plaintiff's medical expert has not competently testified that the Plaintiff has sustained or likely will sustain; (c) stating legal conclusions; (d) accusing Ethicon of failing to comply with FDA requirements; (e) providing marketing opinions; and (f) setting forth a narrative summary of Ethicon documents.

CONCLUSION

For the foregoing reasons and those set forth in Ethicon's initial brief, the Court should limit Dr. Elliott's opinions in this wave of cases.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this day I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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